

Livensa

Procedural steps taken and scientific information after the authorisation

No	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
R/0016	Renewal of the Marketing Authorisation	19/05/2011	18/07/2011	SPC, Annex II, Labelling, PL	<p>Based on the CHMP review of the available information and on the basis of a re-evaluation of the benefit risk balance, the CHMP is of the opinion that the quality, safety and efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and therefore considered that the benefit risk profile of Livensa continues to be favourable.</p> <p>The CHMP is of the opinion that one additional five-year renewal on the basis of pharmacovigilance grounds is required. The reason for an additional five-year renewal is that the off-label use is a safety risk. It is worrying that the data from the THIN (The Health Improvement Database) study suggests that approx 70% of the users are outside indication. The MAH has been asked to consider how to prevent the off-label use and present it in the next PSUR (6 month).</p> <p>Therefore based upon the safety profile of Livensa, which requires the submission of 6 monthly PSURs, the CHMP concluded that the MAH should submit one additional renewal application in 5 years time.</p>

¹ Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.

² No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.

³ SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

No	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
IA/0015/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer of the manufacturer responsible for batch release, B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings	06/12/2010	n/a	SPC, Annex II, PL	
IA/0014/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer of the manufacturer responsible for batch release, A.1 - Administrative change - Change in the name and/or address of the MAH	13/04/2010	n/a	SPC, Annex II, Labelling, PL	
IB/0012	42_a_01_Change in shelf-life of finished product - as packaged for sale	17/09/2008	n/a	SPC	
II/0011	Update of section 4.8 of the Summary of Product Characteristics and accordingly of the Package Leaflet to add the undesirable effect "abdominal pain", based on the MAH's in-house Clinical Trial database review. Moreover, inclusion of additional information on "hirsutism" as undesirable effect. Update of Summary of Product Characteristics and Package Leaflet	19/03/2008	25/04/2008	SPC, PL	Further to a review of the MAH's in-house Clinical Trial database, and particularly of an analysis of double blind data with 1,645 patients receiving testosterone and 1,455 patients receiving placebo for up to one year, it was observed that the number of adverse events reported and coded to the MedDRA PT "abdominal pain" was significantly higher in the TTS group compared with placebo (1.6% vs 0.6% p=0.0107). The MAH has applied to include "Abdominal Pain" in section 4.8 within the frequency "Common". Moreover, following the outcome of the 2nd PSUR, more restructuring of section 4.8 of the SPC was proposed, including an update of the SPC table and the addition of information on "hirsutism", as undesirable effect. The Package Leaflet has been updated accordingly.

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IA/0010	08_b_01_Change in BR/QC testing - repl./add. manuf. responsible for BR - not incl. BC/testing	12/09/2007	n/a	Annex II, PL	
IA/0009	07_a_Replacement/add. of manufacturing site: Secondary packaging site	09/08/2007	n/a		
IA/0007	38_a_Change in test procedure of finished product - minor change to approved test procedure	09/07/2007	n/a		
IA/0005	38_a_Change in test procedure of finished product - minor change to approved test procedure	09/07/2007	n/a		
IA/0003	15_a_Submission of Ph. Eur. certificate for active substance - approved manufacturer	09/07/2007	n/a		
IA/0002	15_a_Submission of Ph. Eur. certificate for active substance - approved manufacturer	09/07/2007	n/a		
IA/0008	38_a_Change in test procedure of finished product - minor change to approved test procedure	09/07/2007	n/a		
IA/0006	38_a_Change in test procedure of finished product - minor change to approved test procedure	09/07/2007	n/a		
IA/0004	38_a_Change in test procedure of finished product - minor change to approved test procedure	09/07/2007	n/a		
IA/0001	07_a_Replacement/add. of manufacturing site: Secondary packaging site	11/11/2006	n/a		